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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/510,560	02/22/2000	Kenneth Iain Cumming	00.1090.US	3011

7590 07/15/2002

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EXAMINER	
PULLIAM, AMY E	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 07/15/2002 14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/510,560	Applicant(s) CUMMING ET AL.	
	Examiner Amy E Pulliam	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2000* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-39,41,42,47 and 49-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-39,41,42,47 and 49-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of the Request for Extension of Time, the Change of Address, the Information Disclosure Statements, and the Amendment A, all received by the Office on October 2, 2002.

Due to the cancellation of claim 40, the rejections under 35 USC 101 and 35 USC 112 have been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-13, 15-39, 41, 42, 47, and 49-52 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/05903 to Watts *et al.*. Watts *et al.* disclose a drug delivery composition for colonic delivery comprising a drug, and an absorption promoter (p 24, claim 1). More specifically, Watts *et al.* teach that the absorption promoter comprises a fatty acid or a salt thereof, where the fatty acid has between 6 and 16 carbon atoms, for example capric acid or its salt (p 24, claims 1 and 3). Watts *et al.* further teach that the drug can be chosen from insulin, calcitonin, LHRH, buserelin, goserelin, vasopressin, heparin, and more (p 8, l 1-12, and p 24, claim 6). Lastly, Watts *et al.* teach that the composition is formulated in a capsule, tablet, or

pellet which is coated with a material which is dissolved by the conditions found in the intestines, such as a cellulose ester or a methacrylic acid polymer (p 25, claims 8, and 12-14).

Applicant's arguments have been fully considered but are not found to be persuasive. Applicant argues that the reference teaches compositions which are liquid or semi-solids, and further that the reference teaches a liquid or semi solid dispersant. The examiner recognizes that the reference does contain these teachings. However, the examiner directs applicant's attention to page 9, lines 14-17 and 26-29, where the reference teaches that the formulation can also be in tablet or pellet form. Both of these are obviously solid formulations. Applicant has relied solely on applicant's teaching to capsules to rebut the rejections of the prior office action, without considering the teachings to tablets and pellets.

Applicant further argues that the reference does not teach a composition prepared from constituents which are all solids at room temperature. The examiner respectfully disagrees with this argument. First, there is no specific teaching that the tablets are made from constituents which are not solids at room temperature. Each of the examples describe the making of capsules. It is the position of the examiner that dry compression to make tablet formulations is well known in the pharmaceutical art, and applicant's have provided no evidence to show that the reference does not use dry blending when making tablet formulations. Furthermore, although each of the examples on the reference discusses capsule formulation, neither applicant nor a reference inventor is held to only their preferred embodiments. Lastly, applicant is claiming a composition, not a method of making a composition. Therefore, the state of the constituents, prior to their use in making the formulation does not render patentable weight to a composition

claim. In order to render patentable distinction, applicant must display through scientific data and evidence that the two final products differ in their composition, as a result of the state of the original constituents.

For these reasons, the above rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-39, 41, 42, 47, and 49-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watts et al, as discussed above. Watts *et al.* are discussed above as teaching a formulation with a drug and an enhancer, as well as a rate controlling coating. Applicant does not specifically state that the coating can be HPMC, as claimed in applicant's claim 14. However, it is the position of the examiner that one of ordinary skill in the art would have been motivated to use any rate controlling polymer which is well known in the pharmaceutical art on the formulation disclosed by Watts *et al.*. the expected result would be a successful controlled release formulation. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant's arguments have been considered and are not found to be persuasive for the reasons discussed above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

aep
July 12, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600